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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/921,252 | 08/02/2001 | Anne Hover | A227.12-0057 | 9889 |

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EXAMINER

BAXTER, JESSICA R

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

3731

3

DATE MAILED: 04/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/921,252

Applicant(s)

HOVER ET AL. *CW*

Examiner

Jessica R Baxter

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 August 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-28 and 31-34 is/are rejected.
- 7) ☒ Claim(s) 29 and 30 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2. 6) ☐ Other: _____

DETAILED ACTION

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-12 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 6,296,645 to Hover et al.

Although the conflicting claims are not identical, they are not patentably distinct from each other because they both claim an intramedullary nail formed of metal with a non-metal spacer.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1-11 and 21-28 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,935,127 to Border.

Regarding claims 1 -5 and 8, Border discloses an intramedullary nail comprising a nail structure formed of metal (nail 10) with a window defined in an exterior side of the nail and extending through the nail to form a second window having a different length and a width. (slot 17) and a first spacer and second spacer formed of a non-metal, bioresorbable material (solid resorbable material 19) with a nail structure cannula extending therethrough (FIG. 3 bore 16).

Regarding claim 6, Border discloses a bend in the nail structure (Column 2 lines 61-65).

Regarding claim 7, Border discloses that the first window width is greater than the first window width (FIG. 1).

Regarding claim 9, Border discloses that the first spacer fills the first window prior to anchoring of a bone fastener (Column 2 lines 45-49 and Column 3 lines 3-9).

Regarding claim 10, Border discloses that the first window is in a distal end of the nail structure and an additional bone attachment hole defined in the proximal end of the nail structure (bore 22). The terms “distal” and “proximal” are relative terms. If the window (slot 17) is in the distal end then the attachment hole (bore 22) is in the proximal end.

Regarding claim 11, Border discloses that the first window is in a distal end of the nail structure and the nail structure includes an opening (bore 16) longitudinally spaced from the first window and in the distal end of the nail structure. The term “distal” is a relative term.

Regarding claims 21 and 26-28, Border discloses that the bone fastener (fastener 34) has a thickness less than the first window longitudinal length and a width which is less than the first window (FIG. 3 and Column 2 lines 37-39).

Regarding claims 23-25, Border discloses that the screw may be inserted into the spacer in different orientations and placements (Column 3 lines 2 –18).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 13-20 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Border '127. Border discloses the claimed invention except for the step of inserting the spacer transversely into the first window. Border discloses that the solid resorbable portion of the nail is secured to the nail by any suitable means (Column 2 lines 45-49). There is no indication that the resorbable material isn't formed and then inserted either through the bore or transversely through the slot in the side of the nail. It would have been obvious to one having ordinary skill in the art at the time the invention was made to insert the spacer of Border into the slot transversely since there is no indication that the spacer may not be inserted that way.

7. Claims 32-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Border '127. Border discloses the claimed invention except for the step of providing a kit with a plurality of inserts with different chemical properties such as different rates of absorption. Border discloses that different bioabsorbable materials may be used to control the rate at which the spacer is absorbed (Column 3 lines 57-65). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the method of Border with a kit of different materials in order to allow the surgeon to select a suitable material for the procedure.

Regarding claim 34, it is well known in the art to keep surgical instruments and implants in a controlled environment prior to their use or implantation.

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Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

The following references are cited to further show the state of the art with respect to intramedullary nails:

U.S. Patent No. 6,019,761 to Gustilo

U.S. Patent No. 6,309,392 to Alexander et al.

U.S. Patent No. 6,053,918 to Spievack

U.S. Patent No. 6,488,684 to Bramlet et al.

U.S. Patent No. 6,106,528 to Durham et al.

PG-PUB 2002/0151898 to Sohngen et al.

U.S. Patent No. 6,228,086 to Wahl et al.


PG-PUB 2003/0018336 to Vandewalle


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica R Baxter whose telephone number is 703-305-4069. The examiner can normally be reached on M-F 8:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano can be reached on 703-308-2496. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3590 for regular communications and 703-305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Jessica R Baxter
Examiner
Art Unit 3731


jrb
April 4, 2003


MICHAEL J. MILANO
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700